REMARKS

1. Support for the Amendments

Claim 1 is amended to incorporate the subject matter of Claim 8.

In accordance with the above amendments, Claims 7, 10 and 11 are amended to include the term "pharmaceutical aqueous preparation" in place of "pharmaceutical preparation".

Further, in Claim 7, the compounds are limited to those specifically disclosed in the specification on page 20, line 35, to page 21, line 10.

2. Rejection Under 35 U.S.C. Section 112, Second Paragraph 2-1. Claim 5

The Examiner rejects Claim 5 as being indefinite. Specifically, the Examiner asserts that Claim 5 recites the broad recitation of a packaging container, which has an average light transmittance of 20% or lower in the wavelength range from **350 nm to 450 nm**, and the claim also recites a packaging container, which has an average light transmittance of 20% or lower in the wavelength range from **365 nm to 430 nm**, and an average light transmittance of 20% or lower in the wavelength range from **350 nm to 430 nm**, which are narrower statements of the range/limitation.

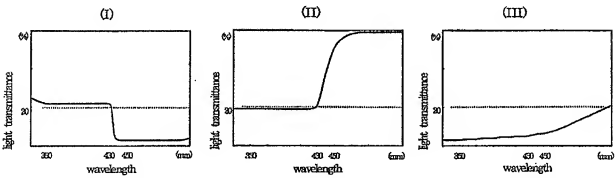
However, the Examiner's assertion is groundless for the following reasons.

Hereunder, the condition having an "average light transmittance of 20% or lower in the wavelength range from **350 nm to 450 nm**" is referred to as Feature A, that having an "average light transmittance of 20% or lower in the wavelength range from **365 nm to 430 nm**" is referred to as Feature B, and that having an "average light transmittance of 20% or lower in the wavelength range from **350 nm to 430 nm**" is referred to as Feature C.

The widths of the wavelength ranges specified in Features A to C do not directly define the scopes of Features A to C, respectively. The logic is explained below with reference to the relationship between the Feature A and the Feature C.

For example, a material α that exhibits light transmittance as in Fig. A (I) satisfies the requirements of Feature Abut not Feature C. Furthermore, for example, a material β that exhibits light transmittance as in Fig. A (II) does not satisfy Feature A but satisfies the Feature C. In contrast, a material γ that exhibits light transmittance as in Fig. A (III) satisfies both the requirements of Features A and C.

Fig. A



As described above, it does not mean that the scope of Feature A is wider than that of Feature C. This is also true of the relationship between Features A and B, and between Features B and C.

In other words, Features A to C each define different characteristics, and Claim 5 that defines all of Features A, B and C clearly is narrower than the scope of Claims 2 to 4. Accordingly, the description of Claim 5 is clear.

2-2. Claims 12 and 13

The Examiner rejects Claims 12 and 13 as being claimed recitation of a use. As shown above, Claims 12 and 13 are deleted. Therefore, the rejection will become moot.

3. Rejection Under 35 U.S.C. Section 112, First Paragraph 3-1. Claim 7

The Examiner rejects Claim 7 as not meeting the written description. Specifically, the Examiner asserts that there is insufficient written basis for derivatives

of berberine, B2 vitamins, hesperidin, oxyquinoline, and B12 vitamins in the specification.

As shown above, we have limited the compounds in Claim 7 to those actually disclosed in the specification. Therefore, the rejection will become moot.

3-2. Claim 13

The Examiner also rejects Claim 13 as not meeting the enablement requirement. As shown above, Claim 13 is deleted. Therefore, the rejection will become moot.

4. Rejection Under 35 U.S.C. Section 103

The Examiner rejects Claims 1 to 6 and 8 to 13 as being unpatentable over Koichi et al. (JP 2002-234837 Abstract and Machine Translation) in view of Hori et al. (Chem. Pharm. Bull. 47(12), 1999) and Healy et al. (U.S. Patent No. 6066374).

However, Claim 1 of the present invention has patentability over Koichi et al., in view of Hori et al., and Healy et al., for the following reasons.

The present invention as amended above provides pharmaceutical products in which a tranilast-containing pharmaceutical preparation is contained in a packaging container through which the content can be visually observed and which can block light in the wavelength range from 365 nm to 430 nm.

According to the present invention, the following advantages are achieved:
(i) the pharmaceutical aqueous preparation contained in the packaging container can be observed with the naked eye;
(ii) further, degradation of tranilast and/or a salt thereof due to light exposure is remarkably inhibited.

In order to achieve the above excellent advantages, it is important to use the packaging container through which a pharmaceutical preparation containing tranilast and/or a salt thereof can be visually observed and which blocks light in the wavelength range from 365 nm to 430 nm.

In contrast, Koichi et al., merely discloses an aqueous preparation of tranilast with a concentration of 0.05 to 30% (see page 9, claims 1 and 5). Koichi et al., does not teach nor suggest the packaging container through which a pharmaceutical preparation containing tranilast and/or a salt thereof can be visually observed, and is also silent about inhibiting photodegradation of tranilast and/or a salt thereof.

Hori et al., merely discloses evaluations of the photodegradation of tranilast in an oily gel and IOIN (2-Ethylhexyl isononanoate), it does not suggest the relationship between the photodegradation of tranilast in the aqueous preparation and the wavelength.

The photodegradation of tranilast greatly differs in an oily gel and IOIN and in an aqueous preparation. This is clear from the disclosures of Hori et al., for example, that the photodegradation products of tranilast in an aqueous solution were tranilast photodimers, but that tranilast was photoisomerized in an oily gel and IOIN (see page 1715, right column, lines 10-7 from the bottom); photodegradation of tranilast is different depending upon the formulations (page 1716, left column, lines 3 to 5); and tranilast in an oily gel and IOIN was more stable than in an aqueous preparation (page 1716, left column, lines 11 to 12).

Hori et al., discloses that light having a wavelength of 280-360 nm contributes to the photodegradation of tranilast in an oily gel and IOIN (Fig. 5, and page 1716, left column, lines 21 to 23). On the other hand, when Example 2 (Fig. 2) and Comparative Example 5 (Fig. 10) of the present specification are compared, Comparative Example 5 exhibits better light blockage at wavelengths of 280-360 nm, but the tranilast of Example 2 exhibits remarkably better stability in an aqueous preparation. In other words, it can be concluded that the photodegradation of tranilast in an aqueous preparation greatly differs from that in an oily gel or IOIN in view of the disclosures of Hori et al., and the experimental results in the present specification.

Hori et al., does not teach which wavelength range of light should be blocked in order to suppress the photodegradation of tranilast in an aqueous solution. Furthermore, Hari et al., nowhere suggests that light having a wavelength range of 365-430 nm contributes to the photodegradation of tranilast in an aqueous solution. Instead, Fig. 5 of Hori et al., indicates that in IOIN, little photodegradation of tranilast occurs by exposure of light in the wavelength range from 365-430 nm. In contrast, according to the present invention, the photodegradation of tranilast in an aqueous preparation can be inhibited by blocking light in the wavelength range from 365-430

nm. Thus, the present invention achieves unexpected results compared with the invention disclosed in Hori et al.

Healy et al., discloses that "the USP requires that medicinal agents which are intended for oral or topical administration must be stored in a container which permits transmission into the container of no more than 10% of ultraviolet and visible light having a wavelength of between 290 nm to 450 nm". However, this USP regulation is directed to solid agents (Column 1, line 27). Furthermore, Healy et al., discloses "a container which permits transmission into the container of no more than 10% of ultraviolet and visible light having a wavelength of between 290 nm to 450 nm while at the same time allowing visual observation of the contents of the container" in Claim 1, etc., but this container is intended to accommodate a solid agent.

As described above, Healy et al., merely teaches the characteristics of a container for accommodating a solid agent, and it nowhere teaches or suggests the characteristics of a container for accommodating an aqueous preparation.

Accordingly, there is no reason for combining the teachings of Healy et al., which relate to a container for accommodating a solid medical agent with those of Koichi et al., which relate to a container for accommodating an aqueous preparation of tranilast.

Furthermore, Healy et al., does not disclose either tranilast nor photodegradation of a solid medical agent accommodated in a container. Healy et al., does not even suggest the technique for suppressing the photodegradation of a medical agent held in a container.

In view of the fact that the photodegradation of tranilast differs in an aqueous preparation and in an oily gel or IOIN as described earlier, the photodegradation of tranilast should be different between an aqueous preparation and a solid agent.

Accordingly, even referring to the teachings of Hori et al., and Healy et al., a person having ordinary skill in the art could not predict whether or not the photodegradation of tranilast in an aqueous preparation can be prevented by using a container through which light can transmit to such a degree that allows visual observation of the contents of the container.

Therefore, even a skilled artisan cannot predict from the teachings of Hori et al., and Healy et al., which wavelength range of light should be blocked in order to prevent the photodegradation of tranilast in an aqueous preparation.

In view of the above, the invention of amended Claim 1 is unobvious over Koichi et al., in view of Hori et al., and Healy et al.

Further, Claims 2 to 6 and 9 to 10 are dependent on Claim 1, and Claim 11 has substantially identical subject matter to that of claim 1. Therefore, the inventions of these claims are also unobvious over Koichi et al., in view of Hori et al., and Healy et al.

The Examiner rejects Claim 7 as being unpatentable over Koichi et al., in view of Hori et al., Healy et al., and Michitoku et al. (JP 04295428 Abstract).

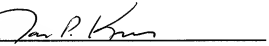
However, as stated above, the invention of amended Claim 1 is unobvious over Koichi et al., in view of Boni et al., and Healy et al., and Claim 7 depends on Claim 1. Therefore, the invention of Claim 7 is also unobvious over Koichi et al., in view of Hori et al., Healy et al., and Michitoku et al.

The Commissioner is hereby authorized to charge any additional fees which may be required with respect to this communication, or credit any overpayment, to Deposit Account No. 06-1135.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

Dated: January 14, 2008



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